ACETIC ACID - acetic acid irrigant
B. Braun Medical Inc.

Urologic Irrigating Fluid for Patients Requiring Prolonged Indwelling Urethral Catheterization.
Not for Transurethral Surgical Procedures.
Not for Injection.

DESCRIPTION

Each 100 mL contains:
Glacial Acetic Acid USP 0.25 g
Water for Injection USP qs
pH: 3.1 (2.8–3.4)
Calculated Osmolarity: 42 mOsmol/liter
The formula of the active ingredient is:

Ingredient	Molecular Formula	Molecular Weight
Glacial Acetic Acid USP	CH_3COOH	60.05

0.25% Acetic Acid Irrigation USP is a prediluted, sterile, nonpyrogenic aqueous solution suitable for urologic irrigation. It contains no preservatives or added buffers. The solution is hypotonic.
The plastic container is a copolymer of ethylene and propylene formulated and developed for parenteral drugs. The copolymer contains no plasticizers and exhibits virtually no leachability. The plastic container is also virtually impermeable to vapor transmission and therefore, requires no overwrap to maintain the proper drug concentration. The safety of the plastic container has been confirmed by biological evaluation procedures. The material passes Class Vl testing as specified in the U.S. Pharmacopeia for Biological Tests —Plastic Containers. These tests have shown that the container is nontoxic and biologically inert.

CLINICAL PHARMACOLOGY

Irrigation of the urinary bladder with acetic acid solution in a concentration of 0.25% has been shown to exert an antimicrobial action against a variety of microorganisms (especially ammonia-forming bacteria) that frequently gain access to the urinary bladder in patients who require prolonged indwelling urethral catheterization. Its antimicrobial action is dependent on administration via the indwelling catheter at a sufficient rate (continuous or intermittent) to maintain an effluent pH of 5.0 or lower. Maintenance of low pH of bladder urine also helps reduce formation of calcium encrustations in the indwelling catheter.

INDICATIONS AND USAGE

0.25% Acetic Acid Irrigation USP is indicated as a constant or intermittent bladder rinse to help prevent the growth and proliferation of susceptible urinary pathogens (especially ammonia-forming bacteria) in the management of patients who require prolonged placement of an indwelling urethral catheter. It also may be used for periodic irrigation of an indwelling catheter to help maintain patency by reducing the formation of calcium encrustations.

CONTRAINDICATIONS

0.25% Acetic Acid Irrigation USP is not for injection.
This solution is contraindicated for irrigation during transurethral surgical procedures.

WARNINGS

FOR UROLOGIC IRRIGATION ONLY. NOT FOR INJECTION.
Use of this solution in patients with mucosal lesions of the urinary bladder may be harmful due to irritation of the lesion. Absorption via open lesions of the bladder mucosa may result in systemic acidosis.
Do not warm above 150°F (66°C).
After opening container, the contents should be used promptly in order to minimize the possibility of bacterial growth or pyrogen formation.
Discard unused portion of irrigating solution since it contains no preservative.

PRECAUTIONS

General

Use aseptic technique when preparing and administering sterile irrigation solutions.
Use only if solution is clear and container and seal are intact.
If pain or hematuria should occur during irrigation, it should be discontinued and the patient reevaluated.
When used for irrigation via appropriate irrigation equipment, the administration set should be attached promptly. Unused portions should be discarded and a fresh container of appropriate size used for the start up of each cycle or repeat procedure. For repeated irrigations of urethral catheters, a separate container should be used for each patient.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies with 0.25% Acetic Acid Irrigation USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Pregnancy Category C
Animal reproduction studies have not been conducted with 0.25% Acetic Acid Irrigation USP. It is also not known whether 0.25% Acetic Acid Irrigation USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 0.25% Acetic Acid Irrigation USP should be given to a pregnant woman only if clearly needed.

Nursing Mothers
Caution should be exercised when 0.25% Acetic Acid Irrigation USP is administered to a nursing woman.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

Geriatric Use
Clinical studies of 0.25% Acetic Acid Irrigation USP have not been performed to determine whether patients over 65 years of age respond differently from younger subjects. Although systemic absorption of the product is unlikely, greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS
Systemic acidosis, pain, and hematuria have been reported in patients receiving urinary bladder irrigation with 0.25% acetic acid solution.
If an adverse reaction does occur, discontinue administration of the irrigant, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination, if deemed necessary.

OVERDOSAGE
Systemic absorption is unlikely unless there are open lesions of the bladder mucosa that have gone undetected. In such event, discontinue the irrigation, evaluate the patient for possible systemic acidosis, intravascular hemolysis, and circulatory overload and institute appropriate countermeasures as indicated. See **WARNINGS**, **PRECAUTIONS**, and **ADVERSE REACTIONS**.

DOSAGE AND ADMINISTRATION
As required for urologic irrigation.
0.25% Acetic Acid Irrigation USP may be administered by gravity drip via an administration set connected to an indwelling urethral catheter designed for continuous or intermittent two-way flow.
For continuous or intermittent irrigation, the rate of administration will correspond roughly to the rate of urine flow and should be adjusted to maintain a urinary effluent pH of 4.5 to 5.0.
Nitrazine or other pH paper may be used to monitor pH, preferably at least four times daily. Drip rate should be adjusted as necessary to maintain desired pH; increasing flow rate reduces pH value and vice versa. With continuous or intermittent irrigation, each patient will require a volume of approximately 500 to 1500 mL per 24 hours.
Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.
This drug product should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED
0.25% Acetic Acid Irrigation USP is supplied sterile and nonpyrogenic in 1000 mL and 500 mL PIC™ (Plastic Irrigation Containers) packaged 16 per case.

NDC	Cat. No.	Size
0.25% Acetic Acid Irrigation USP		
0264-2304-00	R6600-01	1000 mL
0264-2304-10	R6601-01	500 mL

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product. Do not warm above 150°F (66°C).

Rx only

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Directions For Use of PIC Containers
Not for injection.
Aseptic technique is required.

1. Caution – Before use, perform the following checks:
   (a) Read the label. Ensure solution is the one ordered and is within the expiration date.
   (b) Invert container and inspect the solution in good light for cloudiness, haze, or particulate matter; check the container for leakage or damage. Any container which is suspect should not be used.

Use only if solution is clear and container and seal are intact.
Single dose container. Discard unused portion.

2. Outer Closure Removal – Grasp the container with one hand and turn the breakaway ring counterclockwise with the other hand until slight resistance is felt. Then, twisting the container in the opposite direction, turn the breakaway ring **sharply** until the entire outer cap is loose and can be lifted off.

3. Connect the administration set through the sterile set port according to set instructions or remove screw cap and pour.

4. Do not warm above 150°F to assure minimal bottle distortion. Keep bottles upright.

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